

REMARKS

Claim Amendments:

Claim 43 has been amended to specify that the claimed protein comprises at least 38 contiguous amino acids from SEQ ID NO:62. Support for such language can be found in U.S. Patent 5,795,862 to which the instant Application traces its priority claim. Specifically, U.S. Patent 5,795,862 discloses SEQ ID NO:6 which represents the N-terminal 38 amino acids from PfspI. Therefore, Applicants contend no new matter has been entered. Additionally, the requirement that the claimed protein bind an IgE antibody having specificity for PfspI₁₋₅₅ has been removed from the claim.

The term 'flea saliva' protein has been removed from all claims in which it was mentioned. Likewise, the dependency of all dependent claims has been changed from claim 43 to claim 61.

New claim 61 has been submitted. Claim 61 claims the same subject matter as amended claim 43.

New claim 62 has been submitted. Dependent claim 62 adds the limitation of 'flea saliva protein' that was removed from the remainder of the claims.

New claim 63 has been submitted. Support for this claim is found in the specification on page 13, lines 21-23.

Supplemental Oath or Declaration

Applicants again defer the submission of a Supplemental Oath or Declaration or alternatively, an Application Data Sheet, until the deficiency can be properly corrected.

Rejections Under 35 U.S.C. § 112, first paragraph:

The Examiner has rejected claims 43-45, 57 and 58 for lack of written description. Specifically, the Examiner states that the previously submitted claims encompass all proteins comprising a fragment of SEQ ID NO:62 - even the smallest fragment of SEQ ID NO:62, i.e., a single amino acid- that binds an IgE antibody having specificity for PfspI₁₋₅₅. The Examiner, while acknowledging that epitopes likely contain as many as 6 amino acids, further states proteins containing such epitopes could be widely variant in structure and function and the instant

Application discloses only a single representative species of the genus of claimed proteins. Therefore, the Examiner concludes the instant disclosure fails to represent the attributes and features of all species encompassed by the claimed genus.

The claims have been amended to specify the claimed proteins comprise at least 38 contiguous amino acids identical in sequence to at least 38 amino acids from SEQ ID NO:62 or that the claimed protein consists of at least 6 amino acids of SEQ ID NO:62. Applicants note SEQ ID NO:62 is an amino acid sequence of flea saliva protein I (fsPI), and that they have previously disclosed in the priority applications a 38 amino acid sequence from fsPI. Specifically, the sequence of the N-terminal 38 amino acids from fsPI were disclosed in PCT Publication No. WO 96/11271, which was incorporated into the present specification by reference in its entirety. This 38 amino acid sequence is represented by SEQ ID NO:6 in the priority document. Because the amino acid sequence of SEQ ID NO:62 is clearly listed in the instant specification, it is a simple matter to look at the sequence and select 38 contiguous amino acids. Therefore, Applicants contend one of skill in the art has all the information necessary to make a protein within the scope of the claimed invention. With respect to proteins comprising 38 contiguous amino acids from SEQ ID NO:62, Applicants contend it is irrelevant what other sequences lie outside of the selected 38 contiguous amino acid sequence. As long as a protein comprises at least 38 contiguous amino acids identical in sequence to at least 38 amino acids from SEQ ID NO:62, one skilled in the art would recognize that such a protein falls within the scope of the claims. Moreover, with regard to the asserted utilities for the protein, there is little variation among these fragments because all must have a portion of SEQ ID NO:62 that is at least useful in a diagnostic assay.

With respect to the number of species disclosed, Applicants contend they have disclosed more than a single species of the claimed genus. The instant application discloses SEQ ID NO:62, clearly falling within the claims. Priority document WO 96/11271 discloses SEQ ID NO:25 and SEQ ID NO:35. Both of these sequences have regions of at least 38 contiguous amino acids identical in sequence to at least 38 amino acids from SEQ ID NO:62 and therefore fall within the scope of the claims. An alignment of these sequences is shown below for the Examiner's convenience. Additionally, as an illustrative example, an identical region of 38 contiguous amino

acids has been bolded within each protein to demonstrate that all of these proteins fall within the scope of the instant claims.

SIN25 **-----LTSG GKNQDRKLDQ IIQKGQQVKI QNICKLIRDQ PHTNQEKEKC**
SIN35 **WKVKKCTSG GKNQDRKLDQ IIQKGQQVKI QNICKLIRDQ PHTNQEKEKC**
SIN62 **WKVKKCTSG GKNQDRKLDQ IIQKGQQVKI QNICKLIRDQ PHTNQEKEKC**

SIN25 **MKFCTKNVCK GYRGACDGNI CYCSRPSNLG PDWKVNERIE RLPITKILVS**
SIN35 **MKFCTKNVCK GYRGACDGNI CYCSRPSNLG PDWKVNERIE RLPITKILVS**
SIN62 **MKFC-KKVCK GYRGACDGNI CYCSRPSNLG PDWKVskeck dpnnkdsrpt**

SIN25 **GNSSISTTIT NSKYFETKNS ETNEDSKSKK HSKEKCRGGN DRGCDGNVLL**
SIN35 **GNSSISTTIT NSKYFETKNS ETNEDSKSKK HSKEKCRGGN DRGCDGNVLL**
SIN62 **eivpyrqqla ipnick1KNS ETNEDSKCKK HCKEKCRGGN DAGCDGNfcy**

SIN25 **LSTKK-**
SIN35 **LSTKK-**
SIN62 **crpknk**

In view of the above, Applicants contend the instant Application satisfies the written description requirement.

The Examiner has also rejected claims 43-45, 57 and 58 for lack of enablement. Specifically, the Examiner has stated it would require undue experimentation to make all of the proteins that have the stated binding activity and therefore fall within the scope of the claims. Applicants note the requirement for binding activity has been removed so no experimentation would be required to make the instant invention. As noted above, SEQ ID NO:62 is clearly disclosed, therefore enabling one skilled in the art to make proteins comprising 38 contiguous amino acids from the disclosed sequence. Also, one of skill in the art would clearly be able to make and use fragments of SEQ ID NO:62 consisting of at least 6 amino acids. Finally, Applicants again submit that one of skill in the art would be able to use the proteins and fragments for the utilities disclosed in the specification (e.g., in a diagnostic assay), without undue experimentation.

In view of the foregoing amendments and remarks, Applicants respectfully request that the Examiner withdraw the rejection of Claims 43-45, 57 and 58 under 35 U.S.C. § 112, first paragraph.

All of the amended claims are believed to be in condition for allowance. In the event the Examiner has any questions regarding this Application, the Examiner is invited to contact the undersigned representative at (303) 863-9700.

Respectfully submitted,

SHERIDAN ROSS P.C.

By: Angela Sebor

Angela Dallas Sebor
Registration No. 42,460
1560 Broadway, Suite 1200
Denver, CO 80202-5141
(303) 863-9700

Date: Nov. 24, 2003